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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**WASHINGTON, DC 20460**

SAFETY  
ENTION

August 5, 2020

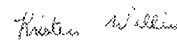
**MEMORANDUM**

Subject: Section 18 Public Health Exemption for SurfaceWise™ 2 for Use at  
American Airlines (AA) Terminals and Facilities in Texas  
File Symbol: 20TX05  
DP Barcode: 458211; Submission#: 1053438  
E-Sub #: N/A

From: Tajah Blackburn, Ph.D., Senior Scientist  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P)



Thru Kristen Willis, Ph.D., Chief  
Product Science Branch  
Antimicrobials Division (7510P)  
Date Signed: 8/5/2020



To: Tawanda Maignan RM 09 / Andrea Conrath  
Emergency Response Team  
Minor Use and Emergency Response Branch  
Registration Division (7505P)

Applicant: Texas Department of Agriculture (TDA)  
P.O. Box 12847  
Austin, TX 78711

**I BACKGROUND**

The Texas Department of Agriculture is requesting a Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), Section 18 Public Health Exemption for the use of 1- Octadecanadium, N, N-dimethy-N-[3-trihydroxysilyl) propyl] chloride, SurfaceWise™ 2, to reduce the spread of COVID-19 by controlling the SARS-CoV-2 virus on surfaces in American Airline (AA) terminals and facilities in Texas. This product is currently unregistered.

The current submission includes the following to support efficacy evaluations:

- Public Health Exemption Application from the Texas Department of Agriculture, dated June 5, 2020
- Confidential Statement of Formula (CSF), unapproved
- Allied Bioscience, Emergency Exemption Application Overview
- Proposed Label (dated 7/26/20)
- Efficacy Supporting Information
  - Gerba et al – AJIC 2015 – Long-term efficacy of self-disinfecting coating in an intensive care unit
  - Ellingson et al – CID 2019—Impact of Novel Antimicrobial Surface Coating on Health Care—Associated Infections and Environmental Bioburden at 2 Urban Hospitals
  - Gerba Transit Whitepaper—Long Term Reduction of Bacteria on Surfaces in Public Buses
  - Gerba et al—medRxiv—2020—A continuously active antimicrobial containing effective against Human Coronavirus 229E
- Additional Information provided following call with TX
  - *SurfaceWise2* Efficacy on Aged Coupons
  - *SurfaceWise2* Coating Durability Study on Aircraft Interior Materials Using XRF
  - SW2 Chemical Abrasion with Bleach, Virex, and Oxivir
  - Bactericidal Activity of ABS-SurfaceWise2 in Suspension

This review also includes an acute toxicity assessment utilizing the following documents:

- SurfaceWise 2 Acute Oral Toxicity (UDP) in Rats, dated 04 May 2020
- SurfaceWise 2 Acute Dermal Toxicity in Rats, dated 04 May 2020
- SurfaceWise 2 Acute Inhalation Toxicity in Rats, dated 29 April 2020
- SurfaceWise 2 Acute Eye Irritation in Rabbits, dated 04 May 2020
- SurfaceWise 2 Acute Dermal Irritation in Rabbits, dated 04 May 2020
- SurfaceWise 2 Skin Sensitization: Local Lymph Node Assay in Mice, dated 04 May 2020

EPA had several calls with Allied Biosciences to discuss follow up technical conversations including but not limited to calls on 7/22/2020, 7/27/2020, 7/31/2020. Studies received after the initial submission as part of follow up discussions are indicated in the table below (\*).

## II FIFRA SECTION 18 PUBLIC HEALTH EXEMPTION SYNOPSIS

Common Chemical Name(s): SurfaceWise™ 2

Active Ingredient(s): 1-Octadecanadium,N,N-dimethy-N-[3-trihydroxysilyl) propyl] chloride

Formulation: Active Ingredient at 0.75% (0.063 lbs active ingredient per gallon)

Manufacturer: Allied BioScience, Inc.  
5000 Legacy Drive, Suite 350  
Plano, TX 75024

Applicators: AA employees or designated applicators. After training on the proper use of electrostatic sprayers.

Sites to be treated: AA aircraft located at AA terminals in Texas (approximately 5 million square feet of treatable surfaces); and AA facilities (approximately 15 million square feet of treatable surfaces) located in Texas.

Intended deployment would include the treatment of all accessible surfaces (e.g. walls, counters, furniture, fixtures, tools and equipment) including:

- Aircraft interiors, including but not limited to restrooms, galleys, cockpits, seats, tray tables, overhead bins and video screens;
- Airport terminals, including but not limited to ticketing, baggage handling and gate areas, jet bridges, Admirals Clubs, and offices;
- On-airport support facilities, including but not limited to, hangars, maintenance facilities, warehouses, fueling facilities, and offices
- Off-airport facilities, including but not limited to, offices, training facilities, warehouses, and maintenance facilities; and
- Aircraft ground support equipment, including but not limited to, push tractors, support vehicles and lifts

**American Airlines and Regional Affiliate Facility Locations in the State of Texas**

<b>Location Name</b>	<b>Address</b>	<b>City</b>	<b>Approx. Treatable SqFt</b>
Abilene Regional Airport	2933 Airport Blvd	Abilene	12,000
Waco Regional Airport	7909 Karl May Dr	Waco	4,500
Rick Husband Amarillo International Airport	10801 Airport Blvd	Amarillo	8,000
Austin-Bergstrom International Airport	3820 Presidential Blvd	Austin	167,000
Jack Brooks Regional Airport	US-69	Taylor Landing	2,700
Brownsville South Padre Island International Airport	700 Amalia Earhart Dr	Brownsville	3,800
Eastwood Airport	1 McKensie Terminal Blvd	College Station	4,200
Corpus Christi International Airport	1000 International Dr	Corpus Christi	30,000
Dallas/Fort Worth International Airport	2400 Aviation Dr	DFW Airport	4,825,000
American Airlines Business Resumption Command Center	5510 Westmoreland	Dallas	195,000
Envoy Air Corporate Headquarters	4303 Regent Blvd	Irving	450,000
Del Rio International Airport	1104 W 10th St	Del Rio	2,100
El Paso International Airport	6703 Comair Rd	El Paso	40,000
East Texas Regional Airport	360 Terminal Circle	Longview	3,100
Killeen-Fort Hood Regional Airport	8101 S Clear Creek Rd	Killeen	3,700
American Airlines Robert L. Crandall Headquarters Campus	1 Skyview Dr	Fort Worth	9,000,000
William P. Hobby Airport	7800 Airport Blvd	Houston	14,000
Valley International Airport	3002 Heritage Way	Harlingen	2,200
George Bush Intercontinental Airport	2800 N Terminal Rd	Houston	80,000
Lubbock Preston Smith International Airport	5403 N Martin L King Blvd	Lubbock	25,000
Laredo International Airport	5210 Bob Bullock Loop	Laredo	4,300
Midland International Air and Space Port	9506 La Force Blvd	Midland	4,600
McAllen International Airport	2500 S Bicentennial Blvd	McAllen	14,000
San Antonio International Airport	3800 Airport Blvd	San Antonio	98,500
San Angelo Regional Airport	8618 Terminal Circle	San Angelo	2,800
Wichita Falls Regional Airport	4000 Armstrong Dr	Wichita Falls	5,200
Tyler Pounds Regional Airport	700 Skyway Blvd	Tyler	4,500

**Method of application/**

**Rate of Application:**

Electrostatic sprayer application (requires training)

**Rate of Application**

**(in terms of a.i. and product):**

Product is ready-to-use; no further dilution is necessary. Using an electrostatic sprayer set to apply 1.0 gallons of product per hour (or 1.0 oz of active ingredient per hour). 3200 square feet of surface area can be treated per applicator per hour.

**Maximum number of applications:**

Up to 4 times per year (at approximately 90-day intervals).

**Total Amount of Pesticide to be used (in terms of active ingredients and product):**

- This Section 28 seeks to allow the use of the up to 25,000 gallons of SurfaceWise™2 used as a surface disinfectant to treat up to 80 million square feet of surface area (20 million square feet treated up to 4 times) inside AA aircraft and facilities in the state of Texas.
- 6250 gallons of SurfaceWise™ 2 applied at a rate of 32,000 square feet per gallon will cover 20 million square feet per application.
- Four—6250-gallon application = 25,000 total gallons of SurfaceWise™ 2 or approximately 1575 pounds active ingredient (0.063 pounds active ingredient per gallon SurfaceWise™ 2)

<u>Duration of the Proposed Use:</u>	All year
<u>Restriction and Requirements:</u>	<p>Precleaning of surfaces with an EPA-Registered Disinfecting Cleaner prior to product application.</p> <p>Product application via electrostatic sprayer. Training required on use of electrostatic sprayer application prior to use.</p> <p>Applicators should wear N-95 masks, protective eyewear (safety glasses), long sleeved shirts, and chemical resistant gloves</p> <p>Allow surface to dry completely prior to re-entry (approximately 10 minutes)</p> <p>FOR INTERIOR USE ONLY</p>

#### **Alternative Antimicrobial Products:**

Pesticides approved by EPA for use against SARS-CoV-2 are all contact disinfectants with no residual antimicrobial activity. These products are effective at time of application; however, treated surfaces can quickly become re-infected with human contact. Therefore, while offering immediate disinfecting activity against SARS-CoV-2, the only way to maintain clean surfaces is by reapplication every few hours. It is difficult for AA to shut down or delay planes and facilities, or even parts thereof, as frequently as would be required to depend solely on currently approved antimicrobials to disinfect hard surfaces and reduce the risk of spread of COVID-2019.

There are three categories of EPA registered antimicrobials products with proven residual activity: first, are those that are effective for only a short period of time (1-2 hours); second are paint products designed primarily for application to nursing facilities, non-critical care areas in hospital, doctor's offices, etc. (Sherwin Williams, Sanitizer #1, EPA Reg. No. 64695-1); and thirdly, certain copper surfaces (Antimicrobial Copper Alloys—Group 1, EPA Reg No. 82012-1). None of these products are viable for use by AA.

SurfaceWise™ 2 is applied via electrostatic sprayer to efficiently cover large surface area. The electrostatic sprayer application helps ensure complete surface coverage, whereas current cleaning practices have been demonstrated to miss key areas. It can cover approximately 3,200 square feet per hour.

SurfaceWise™ 2 is highly compatible with multiple surface types and materials commonly found in public spaces

#### **Alternative Cultural Practices**

**Face Masks.** The use of face masks is crucial for health workers and other people who

are taking care of someone infected with COVID-19 in close settings (at home or in healthcare facility).

**Social distancing.** Creating ways to voluntarily increase distance between people in settings where people commonly come into close contact with one another. Specificity priority settings include schools, workplaces, events, meetings, and other places where people gather. You could spread COVID-19 to others even if you do not feel sick.

**Closures.** Temporarily closing child-care centers, schools, places of worship, sporting events, concerts, festivals, conferences, and other settings where people gather.

**Wash your Hands.** Frequently/often wash your hands with soap and water (20-second minimum). If soap and water are not available, use an alcohol-based hand rub (use a hand sanitizer that contains at least 60% alcohol).

**Routinely Clean.** Clean frequently touched surfaces on a regular basis.

**Don't Touch Your Face.** Avoid touching your eyes, nose, and mouth with unwashed hands.

**Stay Updated.** The state of COVID-19 evolves daily. Make informed decisions based on facts, not fear. To see the most up-to-date information and to monitor travel advisories, visit Texas EDEN, DSHS, and CDC websites.

Detailed explanation of why currently registered pesticides are not adequate and/or effective to the degree needed to control the emergency: No information provided.

Effectiveness of proposed use: Efficacy data by way of peer-reviewed publications and other studies have been provided.

Discussion of risk information:

#### Toxicity of Trimethoxysilyl Quats

A brief overview of the toxicity of the trimethoxysilyl quats is presented below. Further information on the toxicity of this compound can be found in Appendix C in a risk characterization document dated February 2, 2000.

#### *General Toxicity Observations*

Upon reviewing the available toxicity information, the Agency has concluded that there are no endpoints of concern for repeated oral or dermal exposure to the trimethoxysilyl quats. This conclusion is based on low toxicity observed in acute, subchronic and developmental studies conducted with the trimethoxysilyl quat compounds. The risk from inhalation exposure has not been characterized and an additional study designed to assess inhalation toxicity over time may be needed. In addition, severe toxicity has been observed with regard to skin and eye irritation.

### *Carcinogenicity Classification*

There are no concerns for carcinogenicity for the trimethoxysilyl quats based on the results of the mutagenicity studies and the lack of any systemic toxicity being observed in the toxicity database; therefore, no carcinogenic analysis is required.

### *Environmental Risk*

This product is intended for interior use.

Because there are no anticipated pesticide releases, no ecological effects nor environmental risks are anticipated.

### Coordination with other affected State and Federal agencies:

The following state/federal agencies were notified of the Texas Department of Agriculture's (TDA) actions to submit an application for a specific exemption to EPA:

- Texas Commission on Environmental Quality (TCEQ), Air Quality Control
- Texas Commission on Environmental Quality (TCEQ), Water Quality
- Texas Parks and Wildlife Department
- U.S. Fish and Wildlife Department

Notification of registrant: Allied BioScience, Inc., has been notified of this agency's intent regarding this application. Allied BioScience, Inc. also provided a copy of a label with the use directions for this Emergency Exemption Use (although this use is dependent upon the approval of this Section 18 by EPA).

Description of the proposed enforcement program: The State Legislature has endowed TDA with the authority to regulate the distribution, storage, sale, use and disposal of pesticides in the state of Texas. In addition, the EPA/TDA grant enforcement agreement provides the Department with the authority to enforce the provisions of the FIFRA, as amended, within the state. Therefore, the Department is not lacking in authority to enforce the provisions of an EPA Pesticide Enforcement Specialist will make a number of random, unannounced calls on applicators to check for compliance with provisions of the specific exemption. If violations are discovered appropriate enforcement will be taken.

### Repeat Use

This is the first time TDA has applied for this Public Health Exemption.

### Progress Towards Registration

- Acute GLP 6 pack completed
- Micro data in progress
- Chemistry data in progress

### Name of the Pest

- Pest common name: Coronavirus, Novel Coronavirus
- Pest scientific name: SARS-CoV-2

- Disease Transmitted: COVID-19

#### Vectored Disease Transmission and Magnitude of Health Problems

Person-to-person spread. The virus is thought to spread mainly from person-to-person.

- Between people who are in close contact with one another (within about 6 feet)
- Through respiratory droplets produced when an infected person coughs, sneezes or talks.
- These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.
- Some recent studies have suggested that COVID-19 may be spread by people who are not showing symptoms.

Contaminated Surfaces. It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes. This is not thought to be the main way the virus spreads, but we are still learning more about this virus.

#### Treatment of the Health Problem

Comprehensive Infection Control Guidance for Healthcare Professionals about Coronavirus (COVID-19)

[ HYPERLINK "<https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html>" ]

Availability of medical treatment to remedy any resultant health problem associated with the spread of the pest:

- There is no vaccine to prevent COVID-19
- There is medicine to treat COVID-19

Healthcare providers and those that fall ill can focus on treating the symptoms:

- Get plenty of rest
- Drink fluids to prevent dehydration.
- Take medicine to reduce fever and pain.

If taking medicine for another medical condition, one should discuss with their healthcare provider before taking additional medication

### **III PROPOSED LABEL**

**Submitted: 07/26/2020**

Authorized Users: For sale only to American Airlines. Only for use or application by users trained and authorized by Allied BioScience, American Airlines, or by users under their direct supervision. Users must be trained in the application of *SurfaceWise2®* by electrostatic sprayer or equivalent prior to use.

Product Application: Product is for use in aircraft and facilities on hard, non-porous surfaces in the following locations:



**American Airlines and Regional Affiliate Facility Locations in the State of Texas**

Location Name	Address	City	Approx. Treatable SqFt
Abilene Regional Airport	2933 Airport Blvd	Abilene	12,000
Waco Regional Airport	7909 Karl May Dr	Waco	4,500
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San Angelo Regional Airport	8618 Terminal Circle	San Angelo	2,800
Wichita Falls Regional Airport	4000 Armstrong Dr	Wichita Falls	1,200
Tyler Pounds Regional Airport	700 Skyway Blvd	Tyler	4,500

**Total Coverage:** Up to 80 million square feet of surface area (20 million square feet treated up to 4 times) inside American Airline Aircrafts and facilities in the state of Texas. 6250 gallons of SurfaceWise 2, applied at a rate of 3200 square feet per gallon, will cover 20 million square feet per application.

**Maximum Total Usage:** Four—6250-gallon applications = 25,000 total gallons of SurfaceWise2, approximately 1575 pounds active ingredient (0.063 pounds of active ingredient per gallon of SurfaceWise 2).

Product is intended to help provide residual control of coronaviruses, including SARS-CoV-2, for up to 45 days on hard, non-porous surfaces. The product is to be used in conjunction with the routine cleaning and disinfecting protocols, to provide continuous protection between cleaning and disinfecting regiments.

Prior applications of **SurfaceWise2®**, the surface must be pre-cleaned/disinfected using an EPA registered disinfecting cleaner listed under List N: Disinfectants for use against SARS-CoV-2, [ [HYPERLINK "https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19"](https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19) ]. Follow all applicable label use instructions. DO NOT DILUTE **SurfaceWise2®**. Apply **SurfaceWise2®** immediately following pre-cleaning and disinfecting by approved List N disinfectant/cleaners. **SurfaceWise2®** should be applied by electrostatic sprayer, setting flowrate to 1 gallon of product/hour. Application at this rate will cover approximately 3,200 ft²/hr. Spray surfaces from a distance of 24-36 inches to the point of saturation being careful not to let the liquid start to drip. Be sure to apply to all surfaces paying particular attention to the underside of surfaces. A sheen will be present on the surface following treatment. Following application, allow treated surfaces to completely air-dry (approximately 10

minutes) prior to handling. Aircraft and airline facilities may be re-entered following drying.

Reapply coating at least once every 45 days. The reapplication interval is subject to change based on data and the written concurrence of both the Texas Department of Agriculture and the US Environmental Protection Agency. The average coating density should be maintained at a pre-determined value assessed by abrasion testing, XRF, or other agreed to means.

#### IV SYNOPSIS OF SUBMITTED EFFICACY DOCUMENTS

**Table 1: Summary of Submitted Studies**

Study Number	ABS Product Tested	Type of Study & Duration	Outcome
1	ABS-G2015	Field-ICU, 15 weeks	99% reduction in bacteria
2	SurfaceWise 1	Field- Hospital, 1 year	36% reduction in HAI and reduction in bacteria
3	Unclear	Field- Bus, months, non-peer reviewed	93% reduction in bacteria
4	SurfaceWise 2	Lab- 10 min and 2 hour	Human corona 229E; 10-minute contact time = 1.34 LR 120-minute contact time = > 3.99 LR
5	SurfaceWise 2	Durability, abrasion	None
6	SurfaceWise 2	Lab- coupons stored for 8 weeks	Bacteria; 1 week = 5.29 LR 2 weeks = 5.03 LR 4 weeks = 5.53 LR 8 weeks = 5.30 LR
7	SurfaceWise 2	Durability- 50 cycles w/abrasion and disinfectant	None
8	SurfaceWise 2/ <b>Ex. 4 CBI</b>	Inert vs active test	>99.9% reduction in bacteria for SW2 when compared to <b>Ex. 4 CBI</b>

9*	SurfaceWise 2	Faux leather test with bacteria	>99.9% reduction in bacteria at 2 hours contact time
10*	SurfaceWise 2	Durability assessment against bacteria for contact time of 2 hours	>99.9% following physical abrasion against bacteria
11*	SurfaceWise 2	Efficacy assessment following multiple re-inoculations ( 6 hours) with bacteria for contact time of 2 hours for up to 12 hours	>99.9% reduction with each re-inoculation event.
12*	SurfaceWise 2	Efficacy assessment following multiple re-inoculations with Human Coronavirus 229E for contact time of 2 hours for up to 8 hours	>99.9% reduction with each re-inoculation event.

#### **1. Gerba et al – AJIC 2015 – Long-term efficacy of self-disinfecting coating in an intensive care unit**

- **ABS product tested: ABS-G2015**
  - Consists of both quaternary ammonium silyl oxide and titanyl oxide
  - In discussion with ABS, it was clarified that the ABS-G2015 is the same as SurfaceWise 1 but had an additional titanium dioxide containing sealant applied over the coating.
- Field study conducted in an intensive care unit (ICU).
- 95 sites were selected for the study including bed rails, bed controls, tray table, wall above the sink, 2 ICU nursing stations, waiting lobby countertops, phones, computer keyboards, chair armrests, and end tables. Some objects were removed and were not available for culture at some of the subsequent time points.
- Sample taken before treatment with ABS-G2015, and following treatment at 1, 2, 4, 8, and 15 weeks for total bacteria.

The product was applied with an electrostatic spray applicator on all surfaces in the ICU including hard surfaces (e.g. beds, tray tables, bed rails, walls) and soft surfaces (e.g. drapes, cloth and vinyl-covered chairs) and left to dry.

- During the course of the study, hospital staff maintained their normal daily cleaning schedule which involved disinfecting with reusable cloths containing bleach and/or reusable disposable quaternary ammonium wipes containing

dimethyl ethylbenzyl ammonium chloride and dimethyl benzyl ammonium chloride as active ingredients

- No clinical interventions (e.g. changes in hand hygiene practices) were instituted during this period.
- Areas of 100 cm<sup>2</sup> were sampled using a sponge stick containing Lethen broth to neutralize any residual disinfectant.
- Samples were cultured for total bacteria, *Clostridium difficile*, MRSA, VRE, and carbapenemase- resistant *Enterobacteriaceae* (CRE).
- Study Results: The average bacterial count on all treated surfaces was reduced by >99% (2 logs) for at least 8 weeks after treatment. Overall, average levels of bacteria never returned to those observed before treatment even after 15 weeks. Antibiotic-resistant bacteria were found on 25% of the sites tested before treatment but were isolated at only 1 site during the 15 weeks after treatment.
- Based on the study results, it recommended that the treatment is reapplied every 3-4 months for bacterial reduction.
- **Study Limitations:**
  - No virucidal data were included in the study; just bactericidal
  - ABG2015 is different than the product identified on the draft Confidential Statement of Formula (CSF). Registrant stated that SW1 and ABS-G2015 are the same. CSF for SW1 did not include the titanyl moieties so ABS-G2015 is different.
  - Study did not specify the period of sampling following normal daily cleaning/disinfection.
  - No neutralization effectiveness confirmation information.
  - No controls for surfaces.
  - Baseline data assessments were presented differently than experimental data assessments.
  - No information regarding the type of electrostatic sprayer used in the study
  - Paper is silent regarding true wearability of the treated surfaces. This information is apparently necessary and relevant as demonstrated in the white paper, "Gerba Transit Whitepaper – Long Term Reduction of Bacteria on Surfaces on Public Buses" (described below), where the entrance railing was frequently touched, and the coating was removed by wear.
    - Note: A wearability assessment was provided for 50-wears in a recent attachment using XFR; no testing conducted with any microorganism for the wearability assessment. Abrasion and chemical exposure were conducted separately.
  - No information regarding the type of electrostatic sprayer used in the study

## **2. Ellingson et al – CID 2019 – Impact of a Novel Antimicrobial Surface Coating on Health Care—Associated Infections and Environmental Bioburden at 2 Urban Hospitals**

- **ABS product tested:** SurfaceWise 1
- Study conducted at 2 large American hospitals, identified as Hospital A and Hospital B.

- Prior to applications on the test sites, the surfaces were prepared with a solution containing a mild emulsifying agent on all hard, high-touch surfaces including keyboards, countertops, railings, and chairs, to remove any buildup of organic matter.
- The antimicrobial surface (AMS) coating is a quaternary ammonium polymer. According to the paper, the active ingredient reduces both bacteria and fungus.
- Technicians applied the AMS coating with an electrostatic spray applicator to all hard and soft surfaces in the selected treatment units. For patient rooms, technicians coordinated with hospital personnel to enter room immediately following discharge and terminal cleaning.
- AMS surface coating was applied 3 times, approximately once every 4 months. A complete application took approximately 4 weeks (20 business days)
- Prior to and following the application, hospital staff maintained their normal daily cleaning schedule in all areas, which involved using reusable cloths and disinfecting with hospital-grade disinfectants, such as bleach or quaternary ammonium compounds.
- Post-application sampling took place approximately 11 weeks following application with some variability.
- VRE, CRE, *C. difficile*, MRSA were assessed, along with total bacteria.
- Across both hospitals, there was a 36% decline in pooled HAIs (following an application of AMS coating. In control units, there was no decline in HAIs over the same period. The difference in unit application and control units for pooled HAI was significant.
- There were statistically significant decreases in total CFU levels at both hospitals following applications of the AMS coating.
- **Study Limitations/Questions**
  - SW1 tested (in paper referred to as antimicrobial surface (AMS) coating)
  - The surface preparation process, to include the emulsifying agent, is not described.
  - Not sure if the surface preparation process occurs for each application of the AMS. Not sure if this surface preparation is similar to the use directions on the proposed label.
  - The “complete application” took 4 weeks (20 business days). Why? What did this 4- week process entail?
  - Study did not specify the period of sampling following routine disinfection (not terminal disinfection).
  - Hand hygiene decreased from 90% in the pre-application period to 56% in the post-application period. Was the decline in handwashing an unforeseen consequence of the AMS coating used in the facility (i.e. where hospital staff informed of the presence of the coating; study blinded)?
  - Neutralization effectiveness confirmation information.
  - No virucidal efficacy data; just bactericidal.
  - No information regarding the type of electrostatic sprayer used in the study.
  - No environmental data were collected in the control units; however, the study states that there was no impact in control units across both hospitals.
  - Lack of information pertaining to monthly, unit-specific infection preventions and antimicrobial use data, which could have affected study outcomes.

### **3. Gerba Transit Whitepaper – Long Term Reduction of Bacteria on Surfaces on Public Buses**

- **ABS product tested:** Unclear
- 40 buses out of 220 were sprayed with a silicon-oxide bonds and titanium oxide bonds
- Prior to any treatment, both groups of buses were tested for heterotrophic bacteria on various surfaces in order to establish a baseline profile of each bus.
- Buses used in the tests transported approximately 400 persons.
- Surface samples were taken at five locations in each of the fourteen buses for heterotrophic bacteria: entry railing, fare box, driver compartment, interior railing, and seat back;
- Samples were taken at the end of the working day after the bus returned to the transit facility but before they were cleaned by night maintenance workers.
- Samples were collected in all of the buses before the intervention and then 30 days later.
- On average there were 93% fewer bacteria on the surfaces in the treated buses versus untreated buses based.
- However, with the exception of the entry railing, the bacterial burden at all treated sites was reduced as compared to the untreated sites.
- The greatest difference between treated and untreated buses in bacteria numbers was in the driver's compartment where there were fewer than 99.8% bacteria in the treated busses.

#### **Study Limitations**

- No viruses were tested; just bacteria.
- Not sure what was tested; referred to as silicon-oxide bonds and titanium-oxide bonds (does not appear to be neither SW1 nor SW2).
- The Section 18 application includes the following statement regarding general toxicity "severe toxicity has been observed with regard to skin and eye irritation". How is this addressed for high-touch surfaces (entry railings, etc.) beyond application since the product may be in place for significant period of time?
- No neutralization effectiveness confirmation information.
- No clear indication of the how the "silicon-oxide bonds and titanium oxide bonds" relate to SW2.
- Details regarding surface preparation and spray application were not included.
- Routine cleaning consisted of general sweeping, removal of trash and wiping down railings and other surfaces with a commercial detergent; no mentioned of the disinfectant used.
- Unclear if electrostatic sprayer was used to apply coating.
- No wearability assessment for use conditions.

### **4. Gerba et al—medRxiv--2020 – Antimicrobial Surface Testing of ABS antimicrobial coating, SurfaceWise 2 Against Human Coronavirus 229E**

- Virus tested: Human Coronavirus 229E
- Product applied as electrostatic sprayer
- Contact times: 10-minute and 120-minute contact

#### **Study Limitations**

- Contact times: 10-minute and 120-minute contact, not the 90-days as proposed; not sure when contact time is initiated

- No neutralization effectiveness confirmation information
- No information on cytotoxicity or CPE
- No information regarding the type of electrostatic sprayer used in the study
- Carrier dry time/humidity not included.
- Mentions Sephacryl G-10 as possible neutralization, but not explained in the text.
- Uncertain if the neutralization step was effective (utilized a swab for neutralization) and transfer. Potential to leave virus on the carriers if the virus was spread over the carrier. Publication did not include this detail of information.

#### **5. SurfaceWise 2 coating durability study on aircraft interior materials using XRF**

- Method described three abrasion procedures for determining SW2 coating durability on aircraft interior materials under lab test conditions and compare the erosion patterns with the first generation SurfaceWise coating (SW1) on the same substrates.

#### **Study Limitations**

- No microbiological assessments of the surfaces following physical abrasion.

#### **6. Antibacterial Activity of ABS-SurfaceWise 2 antimicrobial coating remains intact up to 8-weeks after product application**

- Test product was applied to carriers by electrostatic sprayer
- Coupons were stored at room temperature for up to 8 weeks before efficacy assessment
- Treated coupons were inoculated with 0.01 mL of bacterial suspension (*Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Klebsiella aerogenes*).
- Following a contact time of 120 minutes, test carriers are fully submerged in neutralizer broth, briefly sonicated.

#### **Study Limitations**

- Testing against bacteria only.
- No details provided regarding the sonication step

#### **7. SurfaceWise 2 durability and compatibility study with Bleach, Virex and Oxivir**

- Study describes the chemical abrasion procedure for determining SW2 coating durability and compatibility on stainless steel coupons. XRF measurements would be taken on SW2 coating to reflect its durability and compatibility with these chemicals.
- Carriers were cleaned with a soap solution and rinsed.
- Spray SW2 formulation with electrostatic sprayer mounted on the slider at 5 feet far for 4 passes at the speed of 9 ( 1 pass equals one round of sprayer moving from one end to the other end of the slider) and cured overnight.
- After 50 abrasion cycles with bleach, Virex, and Oxivir, SW2 coating had 100% remaining on stainless steel test carriers and the coating appearance did not change before and after chemical abrasion.

#### **Study Limitations**

- No microbiological assessments of the surfaces following chemical abrasion.

#### **8. Bactericidal Activity of ABS-SurfaceWise 2 in Suspension**

- ASTM E1052 “Standard Test Method to Assess the Activity of Microbicides Against Viruses in Suspension” was modified to use a bacterial suspension to determine the bactericidal effects of **Ex. 4 CBI** following a 5-minute contact time.
- The bacterial suspension was added to 4.5 mL of each test substance **Ex. 4 CBI** 2015, and SW2) for 5 minutes at room temperature.

#### **Study Limitations**

- Tested against bacterium; virucidal test was modified to test bacterium.
- Test in suspension instead of carrier-based test.
- Contact time was 5 minutes instead of 90 days.
- Four (4) carriers were used to make the determination for ABS-2015 and SW2; while only 2 carriers were used for **Ex. 4 CBI**

#### **9. Activity of ABS-SurfaceWise 2 as an Antimicrobial Coating when exposed to Bacterial contamination on faux leather**

- Assess the efficacy of ABS-SurfaceWise 2 by applying to faux letter carriers by electrostatic spray application, then testing survivability of bacteria following a contact time of 2 hours.
- Greater than 3 log<sub>10</sub> reduction in bacteria when exposed to SurfaceWise 2 at a contact time of 2 hours.

#### **Study Limitations**

- Tested against bacteria only.
- Contact time limited to 2 hours.

#### **10. Activity of ABS-SurfaceWise 2 as an Antimicrobial Coating when exposed to Bacterial Contamination on Stainless Steel Carriers**

- Coating is applied to carriers using an electrostatic spray application, then survivability against bacteria (*S. aureus* and *P. aeruginosa*) is tested following a contact time of 2 hours.
- Contact time begins upon inoculation.
- One group of test carriers was subjected to an abrasion protocol to assess coating durability and residual efficacy.
- Abrasion test included 30 abrasion cycles equivalent to 60 total passes with a damp cloth. Bacteria were exposed to the abraded surfaces for a contact time of 2 hours.
- *S. aureus* on fresh carriers demonstrated a greater log reduction (4.24) when compared to worn carriers (3.62).
- Both fresh and worn carriers demonstrated a similar log reduction when tested against *P. aeruginosa*.

#### **Study Limitations**

- Tested against bacteria.
- Neutralization confirmation was not conducted for this specific test.
- No soil load included.
- Sonication step included, but not consistently introduced in other tests.



#### **11. Activity of ABS-SurfaceWise 2 as an Antimicrobial Coating when exposed to Repeated Contamination Events with Bacteria**

- Assess the efficacy of ABS-continuously active antimicrobial surface coatings over a prolonged period of time when coatings are subjected to multiple contamination events.
- SW2 is applied to stainless steel carriers using an electrostatic sprayer, then bacteria are inoculated at 2-hour intervals with efficacy evaluation after 2 hours in a series of up to six re-inoculation events (with the re-inoculation events contact period goes up to 12 hours).
- Consistent >99.9% reduction with each re-inoculation event.

##### **Study Limitations**

- Tested against bacteria only.
- Neutralization confirmation information not included in the study.
- Carrier dry time/conditions not included.
- Not sure when contact time really begins

#### **12. Activity of ABS-SurfaceWise 2 as an Antimicrobial Coating when exposed to Repeated Contamination Events with Human Coronavirus 229E**

- Assess the efficacy of ABS-continuously active antimicrobial surface coatings over a prolonged period of time when coatings are subjected to multiple contamination events.
- Antimicrobial coating is applied to stainless steel carriers using an electrostatic sprayer, and then virus is inoculated in 2-hour intervals with efficacy evaluation after 2-hours in a series of four re-inoculation events.
- At the conclusion of the contact time, carriers were swabbed using a cotton-tipped swab saturated with neutralizer broth. The swab was added to 1 ml of neutralizer broth, and then vortexed to release any surviving microorganisms from the swab.
- Log reductions were >99.9% across each contact time for up to 8 hours.

##### **Study Limitations**

- Not sure if neutralization is adequate; method uses a swab for 2" x 2" stainless steel carriers.
- Virus potentially lost in the methods employed (swab, vortexing, etc.).
- Mentions Sephacryl G-10 as possible neutralization, but not explained in the text.
- Carrier dry time/conditions were not included.
- Not sure when contact time is initiated.
- Methods lists contact time of 10 minutes and 120 minutes.
- Neutralization confirmation effectiveness not provided.

On a discussion with Allied on 7/31/2020, Allied stated that this product cannot be used with alcohol-based disinfectants. In addition, prolonged exposure to moisture can inactivate the surface.

## V ACUTE TOXICITY REVIEW

### Active Ingredient:

1-Octadecanaminium,N,N-dimethyl-N-[3-(trihydroxysilyl)propyl],chloride ... 0.75%

### Other

Ingredients.....99.25%

Total..... 100.00%

The stated active ingredient (a.i.) is part of the Trimethoxysilyl Quats, and a RED for Trimethoxysilyl Quats was developed by EPA in September 2007; [ [HYPERLINK "https://archive.epa.gov/pesticides/reregistration/web/pdf/trimethoxysilyl-quats-red.pdf"](https://archive.epa.gov/pesticides/reregistration/web/pdf/trimethoxysilyl-quats-red.pdf) ]).

Note: **Ex. 4 CBI** is listed on the proposed CSF as an inert ingredient. It is unclear based on the data provided if this ingredient is an active or an inert ingredient. For a Section 3 submission, this will need to be determined and additional data will be needed to support this determination.

#### - The submitted acute tox 6-pack:

- The submitted acute tox 6-pack appear acceptable with Toxicity Categories IV for acute oral, acute dermal, and acute inhalation toxicity, eye and skin irritation, and not a skin sensitizer. Although the a.i. at TGA level and products with higher concentrations of the a.i. appear corrosive for eye and skin, the subject product contains only 0.75% a.i. – that might explain the test results and the toxicity categories of the submitted 6-pack.

#### - The proposed draft label:

- No signal word is needed based on the toxicity categories of IV and not a skin sensitizer, according to the Agency Label Review Manual (LRM; [ [HYPERLINK "https://www.epa.gov/pesticide-registration/label-review-manual"](https://www.epa.gov/pesticide-registration/label-review-manual) ] ). If one is used, it must be the one for Toxicity Category III, i.e., CAUTION. The registrant chooses to use Toxicity Category III signal word, i.e., CAUTION.

- No precautionary statement or first aid statement are required based on the toxicity categories of IV and not a skin sensitizer according to the Agency LRM ( [ [HYPERLINK "https://www.epa.gov/pesticide-registration/label-review-manual"](https://www.epa.gov/pesticide-registration/label-review-manual) ] ). The registrant chooses to have the following precautionary statement on the label; “using tobacco” needs to be added:

“Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, **using tobacco** or using the toilet.”

- The registrant chooses to have the first aid statements included on the draft label; they appear acceptable and are consistent with the Agency LRM.

- **PPE:**
  - The registrant requires the following PPE be worn by the applicators:
    - “.....long sleeved shirts, chemical resistant gloves, and NIOSH approved N-95 or KN-95 respirators”
  - The Agency recommends adding “long pants, socks, and chemical-resistant shoes” to the PPE section.

## VI ANALYSES OF SUBMITTED DOCUMENTS

- In response to AD’s questions regarding the similarity of SW1 to SW2, the registrant stated that SW2 has the same active ingredient as ABS-G2015 at the same concentration; however, the registrant failed to explain the role of titanyl oxide moieties (Study #1) and titanium oxide (Study #3). A review of the CSF for SW1 did not include the titanyl oxide moieties associated with ABS-G2015. Therefore, it appears as though SW1, ABS-G2015, and SW2 are each different. A clarification was provided in a follow up call that ABS-G2015 is the same as SW1 but with a sealant. Further, the Ex. 4 CBI justification paper includes yet another product, identified as ABS-2015 (missing the “G”).
- Environmental samples were neutralized with just Lethen broth; however, bleach and other chemistries present in healthcare environments may not have been adequately neutralized with Lethen broth. Subsequently, laboratory studies include D/E neutralizing broth without any neutralization confirmation effectiveness data.
- Out of the four (4) publications submitted to support SW2, three (3) publications were conducted against SW1 or ABS-G2015. A single paper incorporating SW2 against Human Coronavirus 229E was submitted for consideration; however, the contact times were considerably less (10 minutes and 120 minutes) when compared to the proposed contact time (90 days/45 days) included in the Section 18 application.
- From the papers and registrant responses, it appears as though surface preparation extends beyond just using a disinfectant. Study #2 incorporates the use of a degreaser; while the American Airlines (AA) responses to EPA questions includes the use of a “List N chemical disinfectant and surfactant”. The registrant’s response, dated 7/21/2020, stated that AA is referring to choosing a one-step disinfecting cleaner from List N”; however, AA’s revised proposed label does not include this information. The label should be revised with clear, scientifically supported surface preparation instructions for SW2 application.
- A single bacterial study utilizing SW2 incorporated wearability testing with a microbiological assessment. This study was submitted on 7/31/2020. Some wearability field tests (*in situ*) were limited to SW1 and ABS-G2015. Other wearability tests for SW2 used X-ray Fluorescence (XRF) for surface analyses. XRF is a physical test only with no chemical or microbiological assessment. Structural degradation resulting from physical and chemical abrasion may cause

molecular surface changes thereby mitigating efficacy. This cannot be assessed from XRF where only the physical remnants of SW2 are measured. In the absence of SW2 field data, it is difficult to ascertain the product's microbiological residual efficacy following wear. A re-inoculation assessment including Human Coronavirus 229E was provided; however, there are unresolved questions regarding carrier processing (neutralization concerns, etc.) and this test lacks additional information pertaining to the durability of the coating.

- To support the Ex. 4 CBI inert argument, ABS provided a suspension-based test with a 5-minute contact time. This method and test organism are inconsistent with the product's intended application and contact times.
- The application lacks sufficient durability and efficacy data to support residual virucidal claims for SurfaceWise 2 for 45 or 90 days.

## VII RECOMMENDATIONS

1. Additional data is needed to support use of this product as a residual treatment for viruses for 45 or 90 days as specified on the label. Based on the data submitted, claims for duration of efficacy and reapplication should be limited to 1 week. To that end claims such as "Product is intended to help provide residual control of coronaviruses, including SARS-CoV-2, for up to 45- days on hard, non-porous treated surfaces" should be revised to up to 7 days. In addition, the directions for use should be revised to reflect this.
2. The following statement "This product is to be used in conjunction with the routine cleaning and disinfecting protocols, to provide continuous protection in between cleaning and disinfecting regiments" should be revised to "This product is a supplement to routine cleaning and disinfecting protocols...."
3. Additional details are needed on the product label to inform application of the product to include but not limited to: (1) pre-treatment of surfaces prior to application, (2) visual indicators that the coating is disrupted and should be reapplied, and (3) contraindications for products use. Further, the label should state that:
  - a. Alcohol-based disinfectants should not be used on surfaces that are coated, and
  - b. The coating should not be subjected to moisture for prolonged periods of time.
4. A contact time should be added to the label to specify that a 2-hour contact time is needed to achieve a 99.9% reduction in virus.
5. The label should state that this product is not for use on food contact surfaces including but not limited to tray tables and galley carts. All potential food contact surface should be removed from the Section 18 applications as use on these types of surfaces is not supported. There is no tolerance established for this active ingredient or the Ex. 4 CBI
6. Add "long pants, socks, and chemical-resistant shoes" to the PPE section for applicators
7. The Section 18 Emergency Exemption should be granted at 2-month intervals while addition interagency data are generated.



Message

**From:** Dunn, Alexandra [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=426D0177EAAB4001A5C85F051565997E-DUNN, ALEXA]  
**Sent:** 8/21/2020 10:56:03 AM  
**To:** Bolen, Derrick [bolen.derrick@epa.gov]  
**CC:** Gunasekara, Mandy [gunasekara.Mandy@epa.gov]; Hewitt, James [hewitt.james@epa.gov]  
**Subject:** Re: Raw material suppliers for SurfaceWise 2

I'll add something about that.

Alexandra Dapolito Dunn, Esq.  
Assistant Administrator  
Office of Chemical Safety & Pollution Prevention  
U.S. Environmental Protection Agency  
Washington, DC

Sent from my iPhone

On Aug 20, 2020, at 9:00 PM, Bolen, Derrick <bolen.derrick@epa.gov> wrote:

FYI

Thank you,  
Derrick Bolen

Begin forwarded message:

**From:** Mike Ruley <mruley@alliedbioscience.com>  
**Date:** August 20, 2020 at 7:45:14 PM EDT  
**To:** "Bolen, Derrick" <bolen.derrick@epa.gov>  
**Cc:** Stratton Edwards <sedwards@capitolhillcg.com>  
**Subject:** Raw material suppliers for SurfaceWise 2

Derrick,

This email confirms that ALL our ingredients in SurfaceWise 2 are supplied through American Companies.

The table below lists all the ingredients and their suppliers. Please let me know if you have any questions.

Component in Formula	Supplier/s
Ex. 4 CBI	Ex. 4 CBI

Ex. 4 CBI	Ex. 4 CBI
Ex. 4 CBI	Ex. 4 CBI
Ex. 4 CBI	Ex. 4 CBI
Ex. 4 CBI	Ex. 4 CBI

Mike

**Michael Ruley**  
Chief Executive Officer

Allied BioScience, Inc.  
7800 N. Dallas Parkway, Ste. 650 | Plano, TX 75024  
O: 214.432.5581 | M: **Ex. 6 Personal Privacy (PP)**  
<http://www.alliedbioscience.com>  
<image001.png>

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Message

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**From:** Bolen, Derrick [bolen.derrick@epa.gov]  
**Sent:** 8/21/2020 12:16:06 PM  
**To:** Hewitt, James [hewitt.james@epa.gov]  
**Subject:** Re: Raw material suppliers for SurfaceWise 2

Will do.

Thank you,  
Derrick Bolen

On Aug 21, 2020, at 8:11 AM, Hewitt, James <hewitt.james@epa.gov> wrote:

Can you ask Texas to send a quote?

---

**From:** Bolen, Derrick <bolen.derrick@epa.gov>  
**Sent:** Thursday, August 20, 2020 9:01 PM  
**To:** Dunn, Alexandra <dunn.alexandra@epa.gov>; Gunasekara, Mandy <gunasekara.Mandy@epa.gov>; Hewitt, James <hewitt.james@epa.gov>  
**Subject:** Fwd: Raw material suppliers for SurfaceWise 2

FYI

Thank you,  
Derrick Bolen

Begin forwarded message:

**From:** Mike Ruley <[mruley@alliedbioscience.com](mailto:mruley@alliedbioscience.com)>  
**Date:** August 20, 2020 at 7:45:14 PM EDT  
**To:** "Bolen, Derrick" <[bolen.derrick@epa.gov](mailto:bolen.derrick@epa.gov)>  
**Cc:** Stratton Edwards <[sedwards@capitolhillcg.com](mailto:sedwards@capitolhillcg.com)>  
**Subject:** Raw material suppliers for SurfaceWise 2

Derrick,

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Component in Formula	Supplier/s
----------------------	------------



Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

Mike

5

**Michael Ruley**

Chief Executive Officer

Allied BioScience, Inc.

7800 N. Dallas Parkway, Ste. 650 | Plano, TX 75024

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<http://www.alliedbioscience.com>

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